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(54) Title: MINERAL ENRICHED BEVERAGES

(57) Abstract

The use of a sugar alcohol to improve the solubility of a calcium and/or magnesium salt in the manufacture of a calcium or magnesium enriched beverage. A calcium and/or magnesium enriched beverage comprising at least one calcium and/or at least one magnesium salt and a sugar alcohol. A method for increasing the solubility of a calcium and/or magnesium salt in solution comprising adding a sugar alcohol to a solution of a calcium and/or a magnesium salt.

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## MINERAL ENRICHED BEVERAGES

The present invention relates to a nutritional composition, and more particularly to a beverage comprising calcium and/or magnesium and a method of maintaining the calcium and/or magnesium in solution during storage.

It is known that calcium and magnesium are the principal mineral elements of the skeleton and other calcified structures such as teeth; both are needed for healthy development and maintenance of bones and teeth. The mineral elements in these structures are subject to turnover and are needed on a continuing basis for remineralisation of teeth and bone. Health problems (including osteoporosis and dental caries) can arise when the net loss of calcium and magnesium are greater than the rate of remineralisation. Hormonal factors control the utilisation of calcium in the body but a minimum intake of calcium from diet is necessary. The principal types of treatment are:-

Hormone replacement therapy (HRT). This is effective in preventing bone loss which is most marked in women and is at the rate of about 1% per day from age 35 onwards. The loss of bone (osteoporosis) is responsible for fractures and collapse of vertebrae, with resulting loss of stature and morbidity.

Other hormones and vitamins which modulate calcium turnover and conservation such as calciferol, diphosphonates, parathyroid hormone, and calcitonin.

Oral calcium tablets and mixtures may be used therapeutically, alone or in combination with other therapies.

None of the treatments listed above reverse the reduction of bone density which results from the loss of minerals but slow down the rate of loss. Some of the "drugs" for which therapeutic claims are made are not without risk. The first two above work better if there is adequate supplementation of calcium in the diet. Recent clinical studies show that doses of more than 1,000mg calcium per day taken as a dietary supplement are as effective as some hormonal treatments in reducing the rate of bone loss.

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The bones and teeth are the principal storage sites of minerals in the body and in view of daily excretion in urine and faeces of minerals regular replenishment is required.

The recommended daily allowance (RDA) depends on age and physiological condition. The need for additional calcium and magnesium is greatest during period of rapid growth, pregnancy and lactation, and in the elderly where absorption of minerals is less than optimal. There are differences in RDA in various countries eg:-

UK - 500mg Calcium,

USA - 800mg Calcium, 350 mg Magnesium

Canada - 1100mg Calcium, 250mg Magnesium

In generating formulations which meet regulatory requirements of a range of countries, proportions are 1250mg calcium and 250mg magnesium/litre have been used. Formulations may be varied pro rata to provide solutions with more or less minerals content.

Existing mineral supplements which are perceived as 'drugs' are not "patient friendly"; there is therefore a need for a product which can be taken as a nutritional product.

The usual dietary sources of calcium and magnesium are milk and dairy products. These also contain carbohydrate calories (lactose), and half- or full-cream milk contains 2-4% or more of butter fat, and the associated cholesterol. Some consumers dislike milk or are allergic to it. A mineralised drink with a defined content of calcium and magnesium, and which is also socially acceptable is an attractive way of supplementing the intake of calcium and magnesium for subjects at risk.

Mains waters contain variable contents of calcium. Those containing 50-100ppm are classified as "Hard", and the hardest waters contain 150ppm. The hardness is

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caused by dissolved calcium and magnesium salts. "Permanent hardness" is due to silicates and sulphates which remain in solution after boiling; and "temporary hardness" is removed by boiling which converts the soluble bicarbonates to insoluble carbonates.

When ground water saturated with carbon dioxide drains through limestone rocks the carbonic acid so formed reacts with calcium and magnesium carbonates to form bicarbonates which are responsible for temporary hardness. Sparkling mineral waters are carbonated either naturally or artificially, and the dissolved carbon dioxide which is in equilibrium with bicarbonate ion causes the calcium and magnesium salts to remain in solution. Approximately 250ppm represents the maximum amount of calcium and magnesium which can be held in solution in natural mineral waters. On exposure to the atmosphere, these solutions tend to lose carbon dioxide and may become cloudy.

It was has been found that the amount of calcium and magnesium can be increased substantially above this level, and to levels which allow a significant proportion of the RDA of these minerals to be taken as a drink in a convenient volume, by adding one or more calcium and magnesium salts.

Inorganic salts which are candidates as soluble calcium and magnesium sources are:

Chloride - unsuitable at the dose required because of its acrid taste at high concentration. Hypertension?

Sulphate -  $\text{CaSO}_4$  has a pleasant taste but has low solubility,  $\text{Mg SO}_4$  is soluble but has an unpleasant brackish taste.

Nitrate/nitrite - levels of more than 50ppm in drinking water are banned in most countries.

Monophosphate - can be used at certain levels of pH but gives cloudy solutions and may react with other soluble salts to give the insoluble di- and tri-phosphates.

Organic salts of calcium and magnesium are attractive sources of these minerals in drinks. However it was found that at certain values of pH, within the range normally found in beverages, solutions which were clear initially deposited crystals on storage. The search for suitable sources of calcium which can be used to make still or carbonated drinks has been the subject of several studies. The prior art includes:

Japanese Application No. 77/69999, 15 June 1977 describes the preparation of calcium-enriched soft drinks by adding organic salts of calcium produced from sea shells. 3 parts of a 1 : 1 : 1 mixture of calcium citrate, calcium malate and calcium lactate. 3 parts of a 3 : 1 mixture of fructose and invert sugar, 4 parts of a 3 : 1 mixture of orange and lemon juices, and 90 parts water were mixed and conventionally bottled. The calcium used to prepare the calcium salts was made by calcining sea shells at 1,000 - 1,200°C for one hour, treated to remove heavy metals and re-calcined at the same temperature to produce calcium oxide which was dissolved in water and treated with organic acid to yield a calcium salt.

European Patent Application No. 80304177.1, by Monsanto Company, filed 21 November 1990, describes the preparation of amorphous calcium carbonate containing water of crystallisation and which is thereby rendered more readily soluble than crystalline anhydrous calcium carbonate. The use of other, naturally occurring forms of calcium carbonate for preparation of nutritional supplements is well known.

European Patent No. 0507157 granted to Deutsch Granini GmbH (priority date 5 April 1991) refers to the formulation of fruit juices containing calcium lactate, magnesium gluconate and iron (II) gluconate.

International Patent Application No. PCT/US93/09925 by Procter and Gamble (priority date 18 October 1992) describes a sweetener supplement composition and method for production thereof, providing biologically available calcium compounds comprising:

- (a) solubilised calcium
- (b) a defined mixture of citric and malic acid or corresponding acid salts which will react with (a)
- (c) a sugar (preferably fructose)
- (d) water

International Patent Application No. PCT/US93/09926 - Procter and Gamble (priority date 18 October 1993) further defines the ratio of citric and malic acid salts of calcium to provide a stable composition containing sugars.

International Patent Application No. PCT/US/9309927 - Procter and Gamble, claiming priority from 18 October 1993, refers to storage-stable beverage premix concentrates for preparing syrups, beverages and food compositions which are nutritionally supplemented with significant levels of calcium, but not magnesium, and to methods for preparing these concentrates. Further, concentrates have a greater than 10 fold concentration and comprise:

- (a) solubilized calcium
- (b) an edible acid component comprising a defined mixture of citric acid and malic acid

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- (c) an acidic anion component selected from the group consisting of chloride anion, nitrate anion, sulphate ion and mixtures thereof
- (d) an effective amount of a flavour component, and
- (e) from about 5% to about 70% sugar, on a dry weight basis.

The beverage concentrate has a pH of less than or equal to about 4.5, preferably less than or equal to about 3.5 and is stable at temperatures of greater than about 32°C for at least about 4 hours, preferably at least about 3 days.

US patent No. 5422128 describes the composition and preparation of storage-stable, beverage concentrates for preparing beverages and food compositions containing calcium and a mixture of citric acid and malic acid with a defined weight ratio of citric to malic acid. There is also a claim to an acidic anion component selected from a group consisting of chloride, nitrate, sulphate and mixtures thereof.

US Patent No. 5401524 (The Procter and Gamble Company) relates to storage-stable beverage premix concentrates for preparing syrups, beverages and food compositions which are supplemented with calcium and methods for preparing these concentrates. The specifications relate specifically to calcium, and the edible acid component is a mixture of citric acid and malic acid within specified ratios. Additionally, further solubilisation is achieved by addition of 0% - 4% of an inorganic anion. The beverage concentrates are stable at temperatures above 32°C for at least four hours.

US Patent No. 5389387 (The Procter and Gamble Company) describes the preparation of storage-stable beverage concentrates for preparing beverages and food compositions with a supplement of calcium, and a method of

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preparation of the concentrate. The beverage concentrates have a greater than 5-fold concentration. The solutions contain a solubilised calcium component and an acid component comprising a mixture of citric and malic acid.

US Patent No. 5444837 (The Procter and Gamble Company) relates to sweetener supplements which provide a bioavailable source of calcium and are stable (no calcium salt precipitation for at least 4 hours at temperatures of at least 29°C). The mineral content is calcium and the acid component is a mixture of citric acid and malic acid at defined ratios. The formulations also contain sugars.

Each of the patents cited as prior art, rely on

careful definition of the amounts of organic acids particularly citric and malic acid which must both be present to give the solubility effect,

none of the patents refer to the importance of magnesium which is also known to be a structural element in bone,

It has been found by experiment that the use of pre-formed magnesium salts, particularly the lactate and citrate, gives rise to products which have an intense bitter taste. The teaching of these patents cannot be relied upon to arrive at useful compositions as dietary supplements of magnesium and calcium if pre-formed salts are used.

Surprisingly it has been found that a simple and cost-effective way of producing a stable solution of calcium and/or magnesium which is not only free of the bitter taste associated with pre-formed magnesium salts but has an acceptable taste can be achieved by adding calcium and/or magnesium as carbonates, oxides or hydroxides and solubilising in the presence of a polyol. Calcium can be added in the form of a nutritionally acceptable aliphatic or hydroxy aliphatic acids or acid salt. Calcium can also be added in the form of glycerophosphate and acid phosphate.

According to a first aspect of the present invention there is provided the use of a sugar alcohol to improve the solubility of a calcium and/or magnesium salt in the manufacture of a calcium or magnesium enriched beverage.

Preferably the sugar alcohol is selected from glycerol, disaccharide alcohols, tetritols, pentitols, hexitols and heptitols.

According to a second aspect of the present invention there is provided a calcium and/or magnesium enriched beverage comprising at least one calcium and/or at least one magnesium salt and a sugar alcohol.

Preferably, the sugar alcohol is present in an amount of 0.1 to 40% by weight of the beverage, more preferably 0.5 to 20%, and more preferably still about 10%.

Preferably, the calcium and/or magnesium salt is present in an amount of 0.1 to 10% by weight of the beverage, more preferably 0.3 to 5% by weight.

The calcium salt may be selected from one or more of a carbonate, hydroxide, sulphate, nitrate, oxide, acetate, glycerophosphate, gluconate, lactate or monophosphate.

The magnesium salt may be selected from one or more of a carbonate, oxide, hydroxide, acetate,

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glycerophosphate, gluconate or lactate.

Additionally, the beverage may comprise a nutritionally acceptable acid component selected from a mono, di, or trivalent organic acid of an aliphatic or hydroxy aliphatic acid; phosphoric acid; glycerophosphoric acid and gluconic acid.

Preferably, the mono, di or trivalent acid is selected from one or more of citric, fumaric, malic, lactic, adipic and tartaric acid.

Preferably, the acid comprises from 0.1 to 5% by weight of the beverage, more preferably from 0.1 to 2% by weight.

The beverage may additionally comprise one or more of a flavouring, a colouring and a preservative.

Preferably, the beverage has a pH of from about 2.5 to about 6, more preferably from about 3.2 to about 4.1.

The preferred composition comprises calcium and magnesium, which are present in amounts of above 500 ppm calcium and above 75 ppm magnesium, more preferably about 1000 ppm of calcium and about 125 ppm magnesium.

According to a third aspect of the present invention there is provided a method for increasing the solubility of a calcium and/or magnesium salt in solution comprising adding a sugar alcohol to a solution of a calcium and/or magnesium salt.

Whereas previous attempts at mineral supplementation have concentrated on the provision of additional calcium, it is equally important that there is a balance of magnesium and calcium in such supplements. One of the effects of increasing the amount of calcium in diet is to produce a constipating effect; magnesium has the opposite effect. It is therefore beneficial to have a mixture of magnesium and calcium sources in such a supplement.

Preformed magnesium salts which would be expected to be suitable as soluble sources are not practicable because of their bitter taste. A particular example is magnesium lactate which has an unacceptable, very bitter taste and also imparts a distinct colour to the solution. The addition of a polyol to solutions of calcium and/or magnesium compounds helps to mask any after taste. They have a different taste from those formed by the addition of pre-formed calcium and magnesium salts of the same acids.

A feature of the invention is the provision of a pre-mix in the form of a liquid or solid which when added to potable water produces a solution which can be used as a mineral supplement. Such a supplement can be in the form of a "still" mineral-type water, or may be carbonated by addition of 1-4 volumes of CO<sub>2</sub>.

Kirk Othmer (Encyclopedia of Chemical Technology) refers to the solubilisation of calcium salts by sugar alcohols at high values of pH, but does not indicate differences in the activity of individual sugar alcohols, particularly at low pH values. These have

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been discovered by experiment. The choice of sugar alcohol will also depend on regulatory considerations in each territory.

It is suggested in the prior art (and has been confirmed by experiment) that solutions containing the calcium salt of one of malic, citric or tartaric acid are prone to develop crystals which do not subsequently re-dissolve on standing. In the prior art this problem has been addressed by forming soluble and stable calcium salt solutions of calcium malate and citrate. Both organic anions are required to produce a solution stable enough to be useful in practice.

It has been found by experiment that polyols can increase the solubility of calcium and/or magnesium compounds and produce stable solution of malate or citrate, or malate/citrate (ie do not precipitate insoluble crystals on standing). Nutritionally acceptable polyols with at least three hydroxyl groups are effective; diglycol is unacceptable as a food additive. In this specification polyols are polyhydric alcohols as defined in Kirk Othmer (Encycloppedia of Chemical Technology, Third Edition, page 754).

Compositions containing a calcium and/or a magnesium compound, a polyol containing preferably at least three hydroxyl groups and a single di- or tri-basic organic anion or a combination thereof have practical utility in that they can be used to produce mineral supplements containing calcium and magnesium. The inclusion of both calcium and magnesium is preferred since both of these minerals are required for healthy bones and teeth. The use of polyols rather than sugars, has other benefits, for example inhibition of plaque accumulation, suppression of cariogenic bacteria and taste masking properties.

In experiments where solutions of calcium malate were examined as potential calcium sources, there was precipitation of calcium malate after the first freeze-thaw cycle which was not subsequently dissolvable. When 5-10% of concentrated apple juice was added to the solution to provide a flavouring component it was found that precipitation of calcium malate was prevented. Subsequent analysis showed that

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concentrated apple juice contains sugars and also polyols.

Examination of products in the market have shown that some solutions containing soluble calcium salts may precipitate on storage. A method of defining the tendency of calcium-containing solutions to precipitate irreversibly has been devised by subjecting the solution to repeated freeze/thaw cycles. The "Index of Precipitation" described in Figures 1 and 2 refer to the number of freeze/thaw cycles at which precipitation may occur. For practical purposes, solutions which have an Index of Precipitation of 3, ie are stable for at least three cycles, do not precipitate on storage at refrigerator or room temperature during normal shelf life of beverages (3 - 9 months).

Figures 1 and 2 show the effect of increasing concentrations of polyol on the Index of Precipitation. Xylitol and lactitol have a greater solubilising effect than glycerol, sorbitol and maltitol.

Figure 3 shows the stabilising effect of addition of glycerol to a solution containing Calcium malate. The standard solution described is a calcium carbonate slurry neutralised with malic acid to pH 3.8, with no glycerol added.

The solution tested in figures 1 to 3 were  
solutions A to E, which were prepared as per example 1  
below:

## Example 1:

Solutions were prepared from:

	A	B	C	D	E
Calcium carbonate	2.5g	2.5	2.5	2.5	2.5
Magnesium carbonate	0.375g	0.375	0.375	0.375	0.375
Sodium benzoate	0.140g	0.140	0.140	0.140	0.140
malic acid	8.0g	8.0	8.0	8.0	8.0
Glycerol	10-100g				
Maltitol		10-100g			
Sorbitol			10-100g		
Xylitol				10-100g	
Lactitol					10-100g
Water	1000ml	1000ml	1000ml	1000ml	1000ml

The calcium and magnesium carbonate dissolve in the solution with evolution of carbon dioxide. The solution was cooled to 4°C and carbonated with 2.5 volumes of carbon dioxide. The resulting solution contains 1000ppm of calcium and 125ppm of magnesium with a pH of 3.8.

The solution was frozen at -18°C and allowed to thaw (this process causes loss of some dissolved carbon dioxide but does not interfere with the purpose of the experiment). The solution was examined for deposits of crystals which did not re-dissolve at room temperature (25°C). The freeze/thawing cycle was repeated up to ten times. The number of freeze/thaw cycles during which solutions re-dissolve at room temperature (Index of Precipitation) has been found to correlate with stability of solutions at storage temperatures of 4-30°C for several months.

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Other compositions illustrative of the invention are shown in example 2 below:

**Example 2:**

Solutions were prepared from:

	A	B	C	D	E	F
Calcium Carbonate	2.0g	2.0g	1.0g	1.0g	1.5g	1.5g
Calcium Lactate	2.0g	2.0g	2.0g	2.0g	-	-
Calcium Glycerophosphate	-	-	2.0g	2.0g	2.0g	2.0g
Malic Acid	8.0g	-	8.0g	-	8.0g	-
Citric Acid	-	8.0g	-	8.0g	-	8.0g
Magnesium Carbonate	0.475g	0.475g	0.475g	0.475g	0.475g	0.475g
Water	1000ml	1000ml	1000ml	1000ml	1000ml	1000ml

Added to the above variations is a polyol or combination of polyols at the following ranges:

Glycerol	10-100g
Maltitol	10-100g
Sorbitol	10-100g
Xylitol	10-100g
Lactitol	10-100g
Erythritol	10-100g

The calcium carbonate and magnesium carbonate dissolve in the solution giving rise to carbon dioxide release, the other calcium salts dissolve in the solution on stirring. During this time the polyol content is added and the solution allowed to clear. The resulting solution is allowed to cool to 4°C and is carbonated with 2.5 - 3.0 volumes of carbon dioxide. These solutions contain approximately 1000ppm and 125ppm of magnesium with a pH range of 3.2 - 4.1.

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CLAIMS

1. The use of a sugar alcohol to improve the solubility of a calcium and/or magnesium salt in the manufacture of a calcium or magnesium enriched beverage.

2. A use as claimed in claim 1 wherein the sugar alcohol is selected from the group consisting of glycerol, disaccharide alcohols, tetritols, pentitols, hexitols and heptitols.

3. A use as claimed in claim 2 wherein the pentitol is xylitol.

4. A use as claimed in claim 2 wherein the hexitol is sorbitol.

5. A use as claimed in claim 2 wherein the disaccharide alcohol is maltitol or lactitol.

6. A use as claimed in any of claims 1 to 5 wherein the beverage comprises at least one calcium and at least one magnesium salt.

7. A calcium and/or magnesium enriched beverage comprising at least one calcium and/or at least one magnesium salt and a sugar alcohol.

8. A calcium and/or magnesium enriched beverage as claimed in claim 7 wherein the sugar alcohol is selected from the group consisting of glycerol, disaccharide alcohols, tetritols, pentitols, hexitols and heptitols.

9. A calcium and/or magnesium enriched beverage wherein the sugar alcohol comprises from 0.1 to

40% by weight of the beverage.

10. A calcium and/or magnesium enriched beverage as claimed in claim 9 wherein the sugar alcohol comprises from 0.5 to 20% by weight as the beverage.

11. A calcium and/or magnesium enriched beverage as claimed in any of claims 7 to 10 wherein the at least one calcium and/or at least one magnesium salt comprises from 0.1 to 10% by weight of the beverage.

12. A calcium and/or magnesium enriched beverage as claimed in claim 11 wherein the at least one calcium and/or at least one magnesium salt comprises from 0.3 to 5% by weight of the beverage.

13. A calcium and/or magnesium enriched beverage as claimed in any of claims 7 to 12 wherein the at least one calcium salt is selected from one or more of a carbonate, hydroxide, chloride, sulphate, nitrate, oxide, acetate, glycerophosphate, gluconate, lactate or monophosphate.

14. A calcium and/or magnesium enriched beverage as claimed in claims 7 to 13 wherein the magnesium salt is selected from one or more of a carbonate, oxide, hydroxide acetate, glycerophosphate, gluconate or lactate.

15. A calcium and/or magnesium enriched beverage as claimed in any of claims 7 to 14 which further comprises a nutritionally acceptable acid

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component selected from a mono, di, or trivalent organic acid of an aliphatic or hydroxy aliphatic acid; phosphoric acid; glycerophosphoric acid and gluconic acid.

16. A calcium and/or magnesium enriched beverage as claimed in claim 15 wherein the mono, di or trivalent organic acid is selected from one or more of citric, fumaric, malic, lactic, adipic and tartaric acid.

17. A calcium and/or magnesium enriched beverage as claimed in any of claims 15 or 16 in which the acid comprises from 0.1 to 5% by weight of the beverage.

18. A calcium and/or magnesium enriched beverage as claimed in any of claims 15 to 17 in which the acid comprises from 0.1 to 2% by weight of the beverage.

19. A calcium and/or magnesium enriched beverage as claimed in any of claims 7 to 18 which further comprises one or more of a flavouring, a colouring and a preservative.

20. A calcium and/or magnesium enriched beverage as claimed in any of claims 7 to 19 which is an effervescent beverage.

21. A calcium and/or magnesium enriched beverage as claimed in any of claims 7 to 20 which has a pH of 2.5 to 6.0.

22. A calcium and/or magnesium enriched

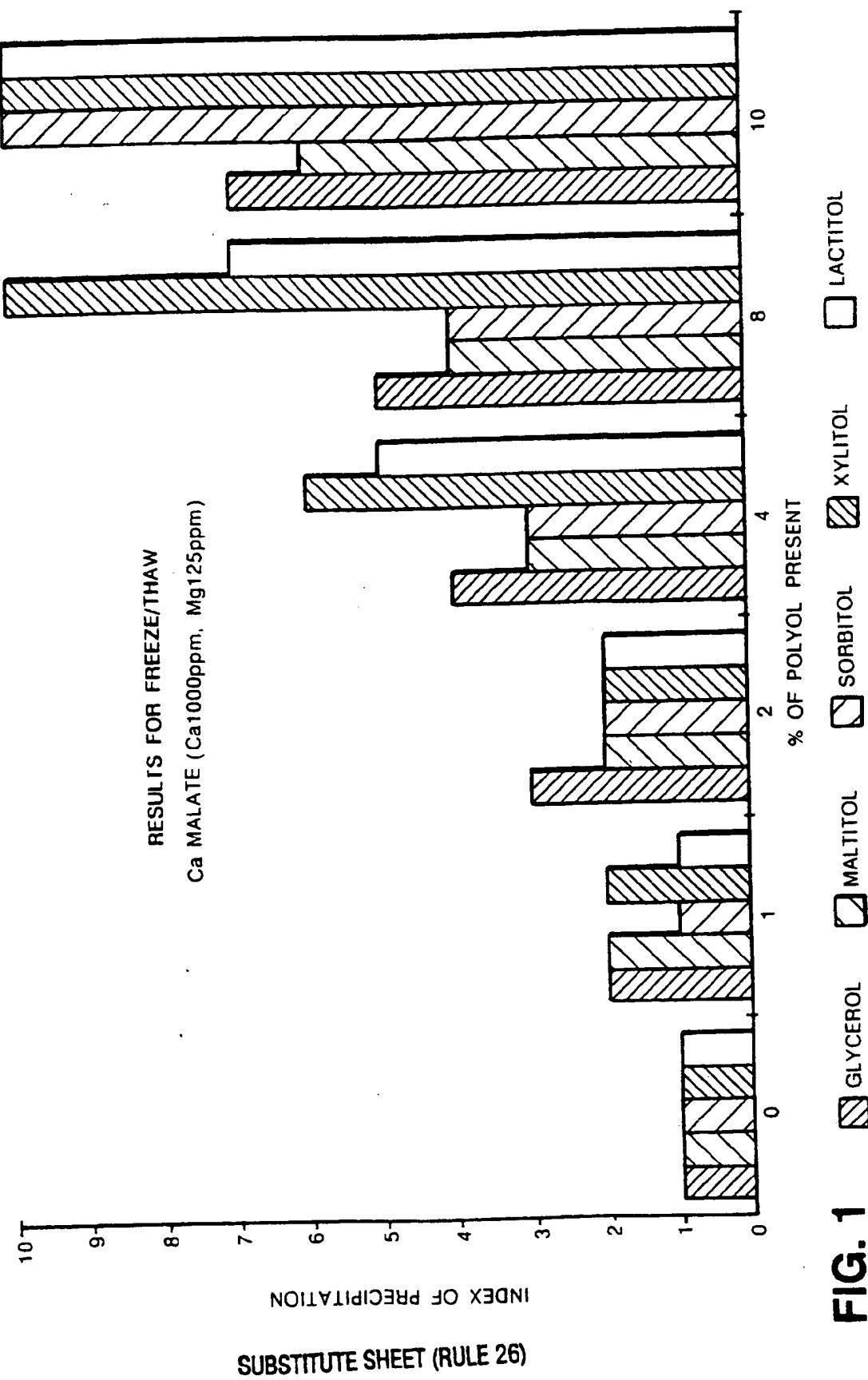
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beverage as claimed in any of claims 7 to 21 which comprises both calcium and magnesium.

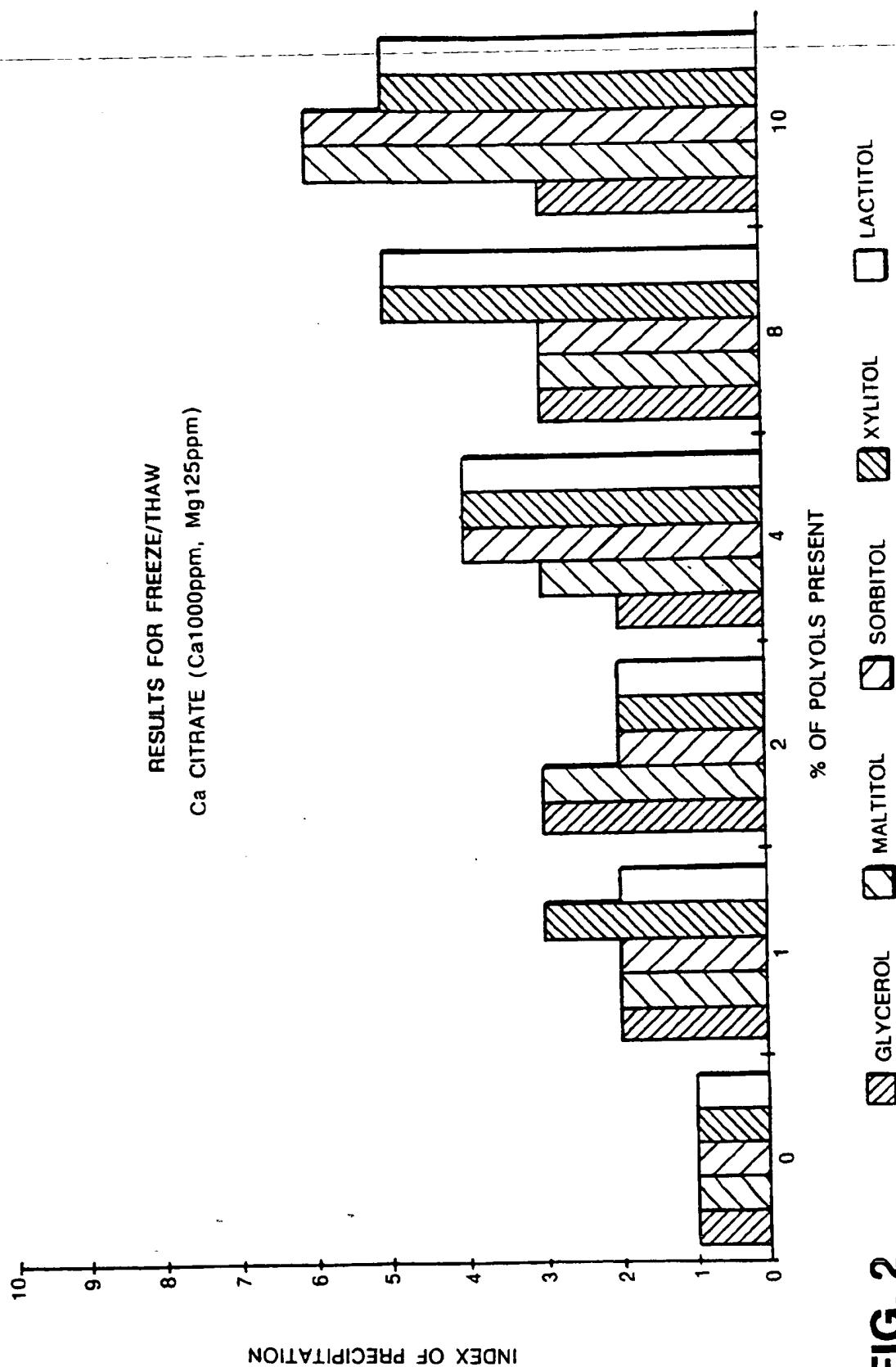
23. A calcium and/or magnesium enriched beverage as claimed in any of claims 7 to 22 which comprises above 500 ppm calcium and above 75 ppm magnesium.

24. A method for increasing the solubility of a calcium and/or magnesium salt in solution comprising adding a sugar alcohol to a solution of a calcium and/or a magnesium salt.

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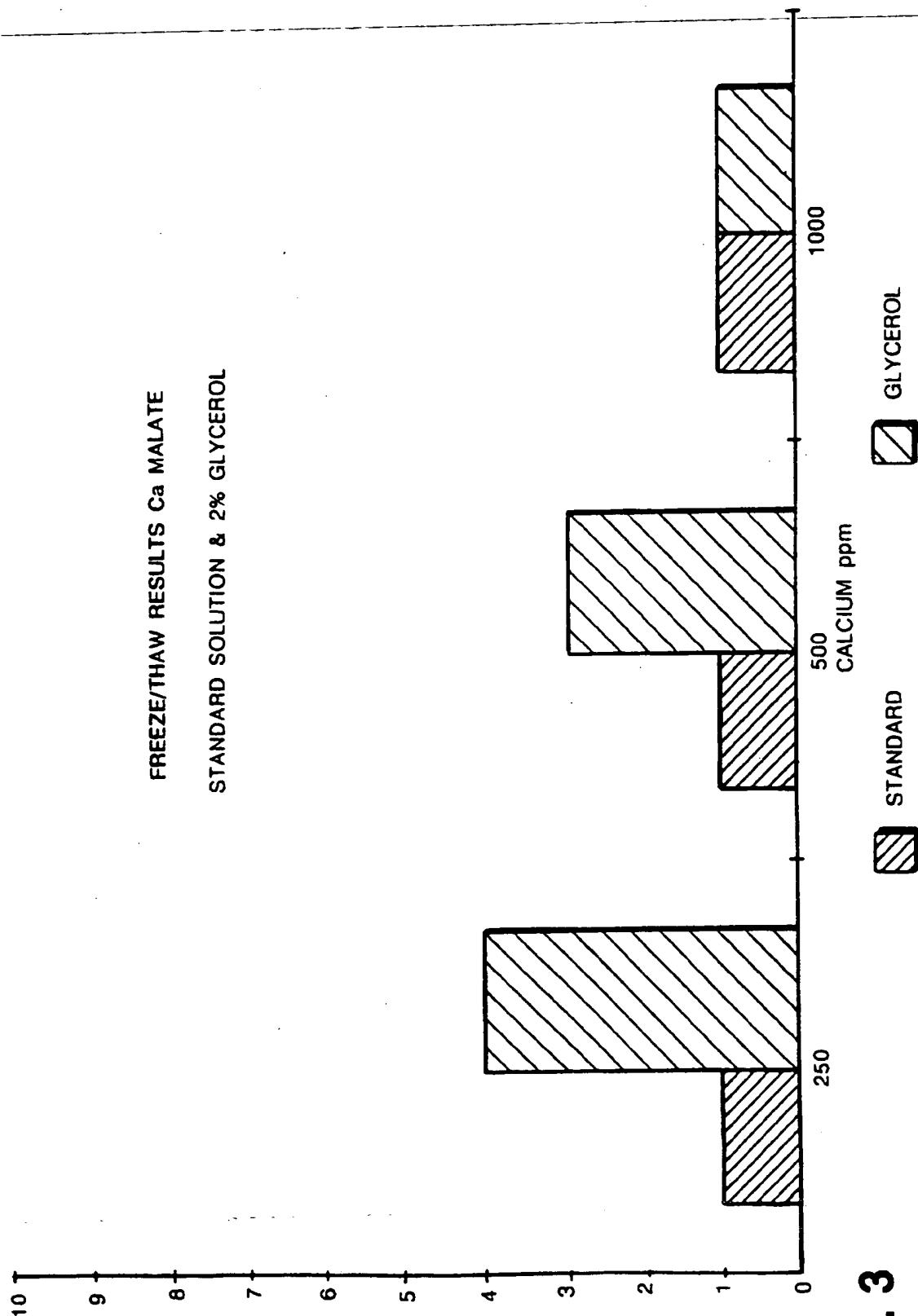
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**FIG. 2**

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INDEX OF PRECIPITATION  
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**FIG. 3**

## INTERNATIONAL SEARCH REPORT

Int. Appl. No.

PCT/GB 96/03038

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 6 A23L1/304 A23L2/38

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 312 249 A (TAKEDA CHEMICAL INDUSTRIES LTD.) 19 April 1989 see the whole document ---	1-24
X	KIRK-OTHMER ET AL.: "Encyclopedia of chemical technology" 1978 , JOHN WILEY & SONS , NEW YORK XP002028555 3d. Edition Vol 1 see page 763 see page 770 ---	24
Y	-/-	1-6

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

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**INTERNATIONAL SEARCH REPORT**

Ink	onal Application No
PCT/GB 96/03038	

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